



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

ENGEL *et al.*

Group Art Unit: 1645

Examiner: N. MINNIFIELD

Appln. No.: 08/468,145

Filed: June 6, 1995

Title: OLIGOPEPTIDE LYOPHILISATE, THEIR PREPARATION AND USE

June 9, 2003

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**RESPONSE TO "NOTICE TO COMPLY WITH REQUIREMENTS
FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE
SEQUENCE AND/OR AMINO ACID DISCLOSURES"**

Mail Stop Sequence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the "Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures" dated April 9, 2003, please amend the application as follows.

I. AMENDMENT

IN THE CLAIMS

Please delete claim 20 and replace it with the following:

20. A method for the preparation of a sterile Cetrorelix lyophilizate, said method comprising the steps of

dissolving Cetrorelix having the amino acid sequence of

AC-D-Nal(2)-D-pCl-Phe-D-Pal(3)-Ser-Tyr-D-Cit-Leu-Arg-Pro-D-Ala-NH₂

(SEQ ID NO: 1)

in aqueous acetic acid to form a solution, wherein the acetic acid has a pH range between 2.5 and 3.0,

diluting said solution with water for injection,

adding bulking agent to the solution, and

sterile filtering, dispensing into injection vials and lyophilizing the solution,

thereby obtaining a sterile Cetrorelix lyophilizate.

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